

CASE N-33563A

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Art Unit: 1761

BOAKANG YANG

Examiner: Becker, Drew E.

APPLICATION NO: 10/091,149

FILED: MARCH 4, 2002

FOR: JUICE BASED BEVERAGE COMPOSITIONS

**MS: Appeal Brief- Patents**

Commissioner for Patents

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APPEAL BRIEF

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## REAL PARTY IN INTEREST

The real party in interest in this appeal is Novartis AG.

## RELATED APPEALS AND INTERFERENCES

There are no other related appeals or interferences.

## STATUS OF THE CLAIMS

Claims 1-8, 10-22, and 24 are pending in this application. Claims 23 and 25-31 are cancelled without prejudice. Claims 1-8, 10-22, and 24 are rejected. Claims 1-8, 10-22, and 24 are appealed.

## STATUS OF AMENDMENTS

There was one amendment made after the final rejection which was entered by the Examiner.

## SUMMARY OF CLAIMED SUBJECT MATTER

The only independent claim in this appeal is claim 1.

Claim 1 relates to an oral nutritional drink which is a clear fruit-juice based beverage composition comprising: (a) a source of protein in an amount from about 0.5 to about 10 wt % of the composition, wherein the protein source is a combination of whey protein isolate and whey protein hydrolysate; (b) a source of carbohydrate in an amount from about 1 to about 30 wt % of the composition; (c) a source of edible acids in an amount from about 0.01 to about 3 wt % of the composition; and (d) a source of fruit juices in an amount from about 5 to about 40 wt % of the composition.

There are no means plus function claims under 35 U.S.C. §112, sixth paragraph in this appeal.

## GROUND OF REJECTION TO BE REVIEWED ON APPEAL

US 6,106,874 to Liebrecht in view of Burke (GB 2335134A); Liebrecht relates to a beverage as a source of calcium (abstract) does not disclose the use of whey protein hydrolysates. Burke relates to a carbonated sports drink of high caloric value for people engaged in physical activities. Burke states that protein hydrolysates have a problem that they tend to precipitate (page 3, lines 22-28), and thus need specific levels of specific carbohydrates to prevent this precipitation. Burke and

Liebrecht are nutritional beverages based on fruit juice, carbohydrate and protein. Can US 6,106,874 to Liebrecht in view of Burke (GB 2335134A) render claims 1-8, 1-20 and 24 unpatentable under 35 U.S.C. §103(a) when protein hydrosylates have a problem that they tend to precipitate and Burke only provides the solution in a specific range of carbohydrate amounts and of carbohydrates of a specific nature?

The Examiner has rejected Claim 21 under 35 USC §103 Liebrecht in view of Burke, in view of Harada (JP 404311378A). Liebrecht and Burke are discussed above and the grounds are herein incorporated. Harado related to a specific fiber supplement. Can US 6,106,874 to Liebrecht in view of Burke (GB 2335134A) , in view of Harada (JP 404311378A) render claims 1-8, 1-20 and 24 unpatentable under 35 U.S.C. §103(a) when protein hydrosylates have a problem that they tend to precipitate and Burke only provides the solution in a specific range of carbohydrate amounts and of carbohydrates of a specific nature?

#### ARGUMENT

Claims 1-8, 1-22 and 24 are argued as a group with claim 1 being representative.

The Examiner has rejected Claims 1-8, 10-20 and 22-24 under 35 USC §103 Liebrecht in view of Burke (GB 2335134A). As admitted by the Examiner, Liebrecht does not disclose the use of whey protein hydrosylates.

Applicants respectfully submit that this rejection is improper because a prima facie case of obviousness has not been established. The three elements of a prima facie case of obviousness are: 1) some suggestion or motivation to modify the reference or combine the teachings; 2) a reasonable expectation of success and 3) the prior art references must teach or suggest all the claim limitations. *Fine* 837 F.2d 1071 (Fed.Cir 1988), *In re Jones* 958 F.2d 347 (Fed.Cir 1992). Burke relates to a carbonated sports drink of high caloric value people engaged in physical activities, and Liebrecht is specifically for providing calcium supplementation. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990). Neither reference suggests the desirability of the combination since their intended uses are dramatically varied. The Examiner states that since both Burke and Liebrecht are nutritional beverages based on fruit juice, carbohydrate and protein. Applicant respectfully disagrees, especially in light of no suggestion in either reference of the desirability of the combination. Applicant submits there is no suggestion or motivation in Burke or Liebrecht to modify the reference or combine the teachings. "Something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making" the

necessary modification. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051 5 U.S.P.Q.2d 1434, 1438 (Fed Cir. ), cert denied, 488 U.S. 825 (1988)

Turning now to the second element of obviousness, there is no reasonable expectation of success. Contrary to a reasonable expectation of success, Burke states that protein hydrosylates have a problem that they tend to precipitate (page 3, lines 22-28), and thus need specific levels of specific carbohydrates to prevent this precipitation; it should be noted that Burke (page 3, lines 22-28) states the problem was solved by adjusting the amount and nature of the carbohydrate used but does not elaborate on the nature of carbohydrate. Further in the present application in paragraph 5 it describes that "The development of fruit juice based beverages containing proteins, carbohydrates, vitamins, and minerals is very difficult. The interaction of the ingredients, particularly the protein with the minerals and other ingredients, often cause the protein to precipitate and frequently cause the entire composition to become very viscous or to gel. Similarly, these interactions may change the physical or chemical properties of the composition in a way that adversely affects the taste, color, odor, mouth-feel and other physical properties of the composition. These adverse changes may occur at any time but are particularly likely when the composition is heated during processing or when the composition sits on the shelf for extended periods. The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. In *re Merck & Co., Inc.*, 231 USPQ 375 (Fed. Cir. 1986); MPEP 2143.02, in this case there is no reasonable expectation of success without undue experimentation. Neither reference teaches or suggests that the addition of protein hydrosylates will illicit a clear beverage and not cause the problems of precipitation when added to a composition as described in the present invention.

In the Advisory Action, the Examiner has asserted that this element is addressed in Burke at page 3, line 28, however, page 3, line 28 does not address the combination of the present invention as claimed. A reading of Burke would not teach one of ordinary skill in the art how to add protein hydrosylates to any mixture without causing the protein to precipitate and not render a clear composition, Burke only discloses a carbonated beverage that will not precipitate on storage with the components and ratios of components described in Burke. Therefore, combination of Burke and Liebrecht are believed to be not proper.

In the Advisory Action the Examiner has asserted that this element (a clear beverage and not cause the problems of precipitation) is addressed in Liebrecht at column 1, line 7, however, column 1, line 7 does not address a clear liquid when protein hydrosylates have been added, which, as argued above would likely cause the protein to precipitate and not render a clear composition. Liebrecht at column 1, line 7 only discloses a clear beverage with the components and ratios of components described in Liebrecht, which, as admitted by the Examiner does not include whey protein.

Even if Liebrecht and Burke were to be combined, the solution proposed by Applicant would not be achieved since they still would not teach how to combine the ratio of ingredients claimed in Claim 1, nor a clear, palatable beverage, without precipitate of the protein.

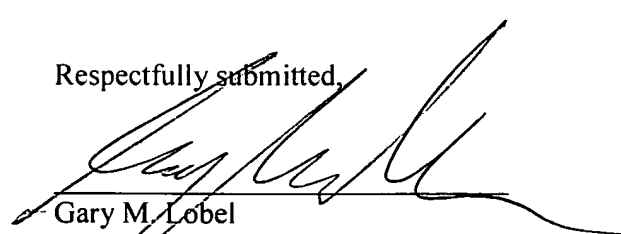
The Examiner has rejected Claim 21 under 35 USC §103 Liebrecht in view of Burke, in view of Harado (JP 404311378A). The arguments for claims 1-8, 10-20 and 24 are relevant for claim 21 and are herein incorporated. There is no motivation to combine Liebrecht, Burke and Harado since Liebrecht is specifically for providing calcium supplementation, Burke is specifically a high calorie sports drink and Harado deals with fiber supplementation. Each designed to address very different issues. There must be a teaching in the prior art for the proposed combination or modification to be proper. In re Newell, 13 U.S.P.Q.2d 1248 (Fed Cir. 1989). There is no such teaching or suggestion in Liebrecht, Burke or Harado, to combine these references.

Applicant submits that even if the skilled person were to combine the teaching of Liebrecht, Burke and Harado, the solution proposed by Applicant would not be achieved. As described above regarding paragraph 5, that "The development of fruit juice based beverages containing proteins, carbohydrates, vitamins, and minerals is very difficult. The interaction of the ingredients, particularly the protein with the minerals and other ingredients, often cause the protein to precipitate and frequently cause the entire composition to become very viscous or to gel." Also as stated above, Burke states that protein hydrosylates have a problem that they tend to precipitate (page 3, lines 22-28), and thus need specific levels and nature of carbohydrates to prevent this precipitation. Since fiber supplements are generally carbohydrates, the solution of Burke would not teach one of ordinary skill in the art how to add a fiber, not disclosed in Burke, to a solution and not have the protein hydrosylates precipitate. Therefore, the combined references would not teach or suggest how to make a clear, palatable beverage, without precipitate of the protein.

FOR THESE REASONS, Applicants respectfully petition this Honorable Board to reverse the rejections of claims 1-8, 10-22 and 24 set forth by the. Should the Board have any questions about the above remarks, the undersigned attorney would welcome a telephone call.

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## CLAIMS APPENDIX

### CLAIMS INVOLVED IN THIS APPEAL

1. (Previously Presented) A clear fruit-juice based beverage composition comprising:
  - (a) a source of protein in an amount from about 0.5 to about 10 wt % of the composition, wherein the protein source is a combination of whey protein isolate and whey protein hydrolysate;
  - (b) a source of carbohydrate in an amount from about 1 to about 30 wt % of the composition;
  - (c) a source of edible acids in an amount from about 0.01 to about 3 wt % of the composition; and
  - (d) a source of fruit juices in an amount from about 5 to about 40 wt % of the composition.
2. (Original) The composition of claim 1 wherein the composition is clear, has a pH of 4.0 or less, and has a viscosity of less than about 40 centipoises.
3. (Original) The composition of claim 2 the composition has a viscosity of less than 20 centipoises.
4. (Original) The composition of claim 1 wherein the source of fruit juices is in an amount from about 10 to about 40 wt %.
5. (Original) The composition of claim 1 wherein the source of carbohydrate comprises from about 5 to about 25 wt % of the composition.
6. (Original) The composition of claim 1 wherein the source of carbohydrate comprises from about 8 to about 20 wt % of the composition.
7. (Original) The composition of claim 1 wherein the source of protein comprises from about 2 to about 8 wt % of the composition.
8. (Original) The composition of claim 1 wherein the source of edible acids comprises from about 2 to about 7 wt % of the composition.

9. (Cancelled) The composition of claim 1 wherein the protein source comprises at least one protein selected from the group consisting of whey protein isolate and whey protein hydrolysate.

10. (Previously Presented) The composition of claim 1 wherein whey protein hydrolysate comprises up to 20 wt % of the combination.

11. (Original) The composition of claim 1 wherein the carbohydrate source comprises at least one carbohydrate selected from the group consisting of sucrose, fructose, HFCS 42, HFCS 55 and maltodextrin.

12. (Original) The composition of claim 1 wherein the source of carbohydrate is a combination of maltodextrin and at least one other carbohydrate selected from the group consisting of sucrose, fructose, HFCS 42, and HFCS 55, and wherein maltodextrin comprises up to about 25 wt % of the combination.

13. (Original) The composition of claim 1 wherein the source of edible acids comprises at least one edible acid selected from the group consisting of citric acid, phosphoric acid, and malic acid.

14. (Original) The composition of claim 1 wherein the source of edible acids comprises a combination of malic acid and at least one other edible acid selected from the group consisting of citric acid and phosphoric acid, and wherein malic acid comprises up to about 30 wt % of the combination.

15. (Original) The composition of claim 1 further comprising from about one-tenth to about three times the recommended daily allowance of one or more minerals.

16. (Original) The composition of claim 1 further comprising at least one mineral selected from the group consisting of calcium, potassium, magnesium, iron, sodium, iodine, molybdenum, chromium, selenium, zinc, and copper.

17. (Original) The composition of claim 1 further comprising at least one water-soluble vitamin.

18. (Original) The composition of claim 1 further comprising at least one vitamin selected from the group consisting of vitamin A, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, panthotenic acid, biotin, folic acid, and niacin.
19. (Original) The composition of claim 1 further comprising up to about 5 wt % of the composition of at least one fiber selected from the group consisting of pectin, cellulose gum, xanthan gum, gum arabic, polydextrose, inulin, and arabinogalactan.
20. (Original) The composition of claim 1 further comprising up to about 5 wt % of the composition of at least one fiber selected from the group consisting of polydextrose, inulin, and arabinogalactan.
21. (Original) The composition of claim 1 further comprising from about 0.5 wt % to about 4% of the composition of at least one fiber selected from the group consisting of polydextrose, inulin, and arabinogalactan
22. (Original) The composition of claim 1 further comprising up to about 0.1 wt % of the composition of at least one fiber selected from the group consisting of pectin, cellulose gum, xanthan gum, and gum arabic.
23. (Cancel) The composition of claim 1 wherein the protein source is whey protein isolate.
24. (Original) The composition of claim 1 wherein the carbohydrate source is a combination of sucrose and fructose.
25. (Cancel) A process for producing a juice based beverage, the process comprising the steps of: forming a protein slurry; forming an aqueous solution containing carbohydrates; mixing the protein slurry and carbohydrate aqueous solution; adding edible acids to the mixture of the protein slurry and the carbohydrate solution; adding fruit juice to the mixture in amounts sufficient to form from about 5 to about 40 wt % of the final composition; adjusting the brix, pH, and temperature of the mixture; and pasteurizing the mixture
26. (Cancel) The process of claim 25 further comprising the step of adding minerals and vitamins to the mixture of protein, carbohydrate, edible acids and fruit juice.



27. (Cancel) The process of claim 25 further comprising adding fibers to the mixture of protein, carbohydrate, edible acids and fruit juice.

28. (Cancel) The process of claim 25 wherein the step of forming the protein slurry comprises mixing a protein selected from the group consisting of whey protein isolate and a combination of whey protein isolate and whey protein hydrolysate, in amounts sufficient to form up to about 10 wt % of the final composition, with water.

29. (Cancel) The process of claim 25 wherein the step of forming an aqueous solution containing carbohydrates comprises dissolving a carbohydrate selected from the group consisting of sucrose, fructose, HFCS 42, HFCS 55, combinations of sucrose, fructose, HFCS 42, and HFCS 55, and combinations of maltodextrin with another carbohydrate selected from the group consisting of sucrose, fructose HFCS 42, and HFCS 55 in water, wherein the carbohydrate is from about 1 to about 30 wt % of the final composition.

30. (Cancel) The process of claim 25 wherein the step of adding edible acids to the mixture of the protein slurry and the carbohydrate solution comprises adding to the mixture an edible acid selected from the group consisting of citric acid, phosphoric acid, combinations of citric acid and phosphoric acid, and combinations of malic acid with another edible acid selected from the group consisting of citric acid and phosphoric acid, wherein the malic acid comprises from about 0.1 to about 50 wt % of the combination, in amounts sufficient to form from about 0.01 to about 3 wt % of the final composition.

31. (Cancel) A process for producing a juice based beverage composition, the process comprising the steps of: (a) mixing a protein selected from the group consisting of whey protein isolate and a combination of whey protein isolate and whey protein hydrolysate in amounts sufficient to form from about 0.5 to about 10 wt % of the final composition with water to form a protein slurry; (b) dissolving a carbohydrate selected from the group consisting of sucrose, fructose, HFCS 42, HFCS 55, combinations of sucrose, fructose, HFCS 42, and HFCS 55, and combinations of maltodextrin with another carbohydrate selected from the group consisting of sucrose, fructose HFCS 42, and HFCS 55, the carbohydrate in amounts sufficient to form from about 1 to about 30 wt % of the final composition, in water; (c) mixing the protein slurry and carbohydrate solution; (d) adding an edible acid selected from the group consisting of citric acid, phosphoric acid, combinations of citric acid and phosphoric acid, and combinations of malic acid with another edible acid selected from the group consisting of citric acid and phosphoric acid,

wherein the malic acid comprises from about 0.1 to about 50 wt % of the combination, in amounts sufficient to form from about 0.01 to about 3 wt % of the final composition to the mixture of protein slurry and carbohydrate solution; (e) adding one or more fruit juices in amounts sufficient to form from about 5 to about 40 wt % of the final composition to the mixture of protein slurry and carbohydrate solution; (f) forming a solution containing one or more minerals in amounts sufficient to supply from about one-tenth to about three times the recommended daily allowance of the minerals; (g) adding the mineral solution to the mixture of protein slurry and carbohydrate solution; (h) forming a solution containing one or more vitamins and optional flavors in amounts sufficient to supply from about one-tenth to about two times the recommended daily allowance of the vitamins; (i) adding the vitamin solution with optional flavors to the mixture of protein slurry and carbohydrate solution; j) adjusting the brix of the resulting mixture to from about 15 to about 20% with water; (k) adjusting the pH of the resulting mixture to less than about 4.0; (l) adjusting the temperature of the resulting mixture to from about 40.degree. F. to about 60.degree. F. (10.degree. C. to 15.degree. C.); (m) transferring the resulting mixture to sealable containers; (n) sealing the containers to produce a pressurized container containing the resulting mixture; and (o) pasteurizing the resulting mixture.

## EVIDENCE APPENDIX

There is no evidence submitted with this Appeal.

## RELATED PROCEEDINGS APPENDIX

There are no other proceedings related to this appeal.